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(71) Applicant: TARGET THERAPEUTICS, INC.
Fremont, CA 94537-5120 (US)

(72) Inventors:
- Kupiecki, David
  Cupertino, California 95014 (US)
- Thach, Cong
  San Jose, California 95132 (US)
- Ortiz, John
  East Palo Alto, California 94303 (US)

(74) Representative: Nicholls, Michael John
J.A. KEMP & CO.
14, South Square
Gray's Inn
London WC1R 5LX (GB)

(54) System for the implantation of liquid coils with secondary shape

(57) An occlusive implant includes an elongated member having an end, a portion proximal to that end, and a portion distal to that end. The proximal portion is sufficiently flexible so that it can be folded upon itself and maintain that configuration without further restraint. At least a portion of the distal portion is preformed to have a first configuration when in a first state and a second configuration when in a second state. The distal portion second configuration has a flow resistance substantially greater than that of the proximal portion. When discharged in the region to be occluded, the proximal portion is forced into a mass around at least a portion of the distal portion secondary structure. As the mass builds in size, it frictionally engages the surrounding vasculature wall and anchors the implant thereto.

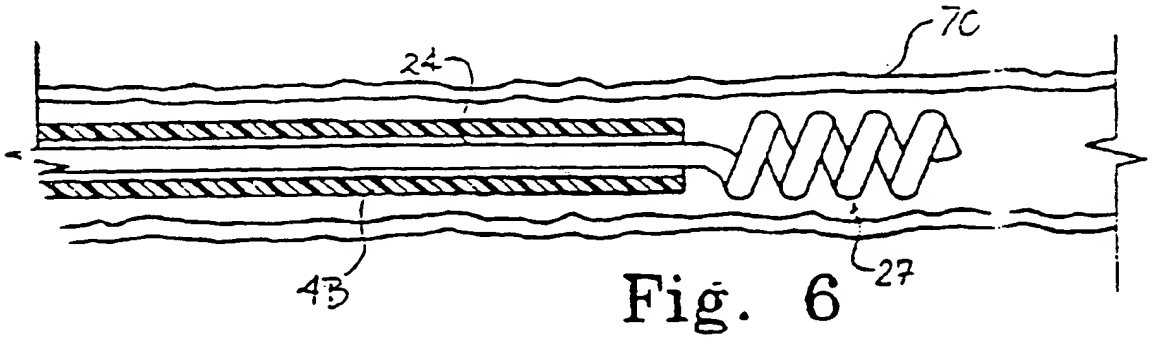

Fig. 6

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Once the distal end of the catheter is positioned at the selected site (its location may be determined by a coating at the distal end of the catheter with a radiopaque material or otherwise affixing such a material to the distal end of the catheter or incorporating such a material into the distal end of the catheter), the catheter is cleared. For example, if a guidewire has been used to position the catheter it is withdrawn from within the catheter.

The plunger in syringe 12, which is loaded with a saline solution, is slowly pushed down to displace the vaso-occlusion device from cartridge 8 down through catheter 4 to the injection site (Fig. 5). As the plunger continues to be pushed inwardly, portion 27 of distal portion 26 is discharged from the catheter where it returns to its secondary configuration (Fig. 6). As the fluid from syringe 12 continues to force vaso-occlusive device 20 from the catheter, the proximal portion is discharged from the catheter and piles against, around and/or in portion 27 in a random fashion to form an occlusive mass. It is believed that since the proximal portion of the vaso-occlusion device has a significantly lower flow resistance configuration than that of the secondary structure in the distal portion, the discharge fluid accelerates the proximal portion through the blood toward secondary windings 28 to form the occlusive mass (Figs. 7 and 8).

The flexibility of the proximal portion described above allows the proximal portion to fold over the secondary windings 28 and remain in that position without the need for external forces or other restraining mechanisms. The proximal portion can, however, become intertwined with secondary windings 28 and other portions of the proximal portion.

As the proximal portion balls up in a dense mass, it expands volumetrically, frictionally engages the inner walls of vessel 70 and anchors the vaso-occlusion device in that position as shown in Fig. 8. The flexibility of the device allows it to ball up as desired under a hydraulic pressure of about 50 to 150 psi. Occlusive masses volumetrically filling about 40-75% of an imaginary sphere that surrounds the mass can be achieved. This high volume packing efficiency facilitates very high occlusion rates.

After the vaso-occlusion device is positioned and/or anchored at the desired site, additional devices may be injected by exchanging the empty cartridge with another loaded with another occlusion device.

Additionally, the method of the present invention may include the step of introducing polymer resins, such as cyanoacrylate resins (particularly n-butylcyanoacrylate) to the intended site after the inventive coils, braids, and chains are in place. That is, the inventive devices form a substrate for these tissue adhesives, or particulate embolization materials such as microparticles of polyvinyl alcohol foam, or various chemotherapeutic agents.

The above is a detailed description of particular embodiments of the invention. It is recognized that departures from the disclosed embodiments may be made within the scope of the invention and that obvious modifications will occur to a person skilled in the art. The full scope of the invention is set out in the claims that follow and their equivalents. Accordingly, the claims and specification should not be construed to unduly narrow the full scope of protection to which the invention is entitled.

Claims

1. An occlusive implant comprising an elongated member having an end, a portion proximal to said end, and a portion distal to said end, said proximal portion being sufficiently flexible so that it can be folded upon itself and maintain that configuration without further restraint, at least a portion of said distal portion being preformed to have a first configuration when in a first state and a second configuration when in a second state, said distal portion second configuration having a flow resistance substantially greater than that of said proximal portion.

2. The implant of claim 1 wherein said proximal and distal portions are contiguous and can be arranged so that the flow resistance of the elongated member is essentially uniform along its length.

3. The implant of claim 1 or 2 wherein said proximal and distal portions can be arranged to have a common longitudinal axis and diameter.

4. The implant of claim 1, 2 or 3 wherein said proximal portion has a generally uniform diameter along its length and said distal portion has a diameter when in its second configuration of at least about twice that of said proximal portion diameter.

5. The implant of claim 1, 2, 3 or 4 wherein said proximal portion assumes a random configuration when generally unrestrained and subjected to fluid pressure.

6. The implant of claim 5 wherein said distal portion substantially maintains its preformed configuration when generally unrestrained and subjected to fluid pressure.

7. The implant of any one of the preceding claims wherein said proximal portion forms at least the same length as said distal portion second configuration.

8. The implant of any one of the preceding claims wherein said distal portion second configuration is generally helical.

9. The implant of any one of the preceding claims wherein said implant is an embolic device.

10. The implant of claim 9 wherein said device comprises a coil.

11. The implant of claim 10 wherein said coil comprises a filament formed into multiple windings, said filament being ≤ 1 mil in diameter.

12. A vaso-occlusive device comprising proximal and distal portions, said proximal portion having a flexibility that provides at least a 20% deflection from its own weight in a 1 cm length thereof, at least a portion of said distal portion having a first configuration when in a first state and a second preformed configuration when in a relaxed state.

13. The device of claim 12 wherein said proximal portion has a length that is at least about 100% the length of said portion of the distal portion when the latter is in said second state.

14. The device of claim 12 or 13 wherein said proximal portion is without a second preformed configuration in its relaxed state.

15. An introducer cartridge comprising:

a first portion having a passage formed therethrough and a region adapted for coupling to a catheter;
an implant disposed in said passage;
a second portion having a recess formed therein and in fluid communication with said passage, and
a blocking member positioned in said recess adjacent to said passage for preventing displacement of said implant thereby.

16. The cartridge of claim 15 wherein said blocking member is perforate.

17. A vaso-occlusive device cartridge assembly comprising:

a vaso-occlusive device having first and second regions, said first region having a primary preformed configuration, and said second region having primary and secondary preformed configurations, said secondary configuration having a flow resistance substantially greater than both of said primary configurations;
a tube that surrounds and restrains said device in a generally linear configuration, said tube having a proximal end to which said first region is adjacent and a distal end; and
an adapter coupled to said proximal end of said tube for coupling a fluid source to said tube.

18. The assembly of claim 17 wherein said primary region has a flexibility that provides at least a 20% deflection from its own weight in a 1 cm length thereof.

19. The assembly of claim 17 or 18 wherein said first region has an axial length that is at least about 100% the axial length of the secondary configuration of said second region.

20. The assembly of claim 17, 18 or 19 further including a blocking member, said tube defining a passage in which said device is disposed, said adapter having a recess formed therein and fluidly coupled to said passage, and said blocking member being positioned in said recess adjacent to said passage and sized for preventing displacement of said device thereby.

21. The assembly of claim 20 wherein said blocking member is perforate.

22. The assembly of claim 20 or 21 wherein said blocking member comprises a filter.